

Remarks

In the present Amendment, claim 84 has been amended to incorporate the limitations of claims 85 and 88, which have been cancelled. Claim 84 has also been amended to remove comparison to a non-tumor tissue or cell sample and to remove optional step (c). Support for these amendments can be found throughout the specification, for example, at page 5, lines 6-19.

Claims 112 and 113 have been amended to incorporate the limitations of claim 88.

Claim 114 has been added to require that the mammalian breast tumor is a human breast tumor. Support for this new claim can be found throughout the specification, for example, at page 10, lines 16-17.

Claim 115 has been added to include the removed step (c) from claim 84 and to require that a mammalian breast tumor likely to respond to a HER-2 directed therapy is identified by increased phosphorylation of S6 ribosomal polypeptide accompanied by decreased expression of IGFR-1 polypeptide and increased expression of NDF. This new claim is supported by the specification, for example, at page 27, line 31 through page 28, line 3, in Table 6, and in original claim 86.

Claims 86 and 89-110 have also been cancelled to further prosecution and allowance of the currently pending claims. Applicants reserve the right to prosecute the subject matter of the cancelled claims in this Application or in a continuing application of this Application.

After entry of this Amendment, claims 84 and 111-115 are pending.

None of the above amendments adds any new matter to the Application as filed.

Each of the objections and rejections raised in the Office Action is addressed separately below.

Rejection under 35 U.S.C. §112, first paragraph

The sole rejection remaining against the claims is a rejection under 35 U.S.C. §112, first paragraph, for the claimed allegedly lacking enablement by the specification.

Applicants have overcome this remaining ground for rejection by the present amendments to the claims.

Applicants respectfully aver that their invention, as presently claimed, is fully enabled by the specification. The claims, as amended, identify a mammalian breast tumor likely to respond

to a HER-2 directed therapy if that tumor has increased phosphorylation of S6 ribosomal polypeptide accompanied by decreased expression of IGFR-1 polypeptide. New claim 115 additionally requires that such a tumor has an increased expression of NDF.

The specification, in Example 4 at page 25, line 6 through page 28, line 14, clearly supports and enables Applicants' claimed invention. There, the specification describes the screening of tissue microarrays taken from breast cancer patients before the patients were treated with Herceptin®. As shown in Table 5 (row labeled IGFR neg/p-S6 pos) and as described at page 27, line 28 through page 28, line 14, of those patients that showed decreased expression of IGFR but increase phosphorylation of S6 ribosomal polypeptide before starting therapy, 67% showed responsiveness to Herceptin® therapy. This is in contrast to non-Herceptin® responsive patients (see, e.g., the patients who had increased IGFR expression and increased S6 phosphorylation).

Thus, Applicants respectfully aver that the specification, as originally filed, fully supports and enables the presently claimed invention. Based on these remarks, Applicants respectfully request that this ground for rejection be reconsidered and withdrawn.

CONCLUSION

Applicants respectfully believe the presently amended claims are in condition for allowance, and so further and favorable consideration on the merits of the claims of record is respectfully requested.

A petition for a one (1) month extension of time is hereby made to respond to the Office Action mailed on January 21, 2010. The Commissioner is hereby authorized to charge the fee required by 37 C.F.R. §1.17, as well as any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-1774, Reference No. CST-213. With the extension, this Response is due on or before May 21, 2010.

If there are any questions regarding this filing, the Examiner is kindly requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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